ZephyrLIFE™ HOME

Patient Guide

Contents

Zephyr Technology

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Introduction

Overview

This manual describes the features, setup and operation of the ZephyrLIFE Home remote patient monitoring system, comprising the Zephyr BioModule, HealthHub and associated sensors.

A companion Quick Reference Guide is provided for clinician use.

Intended Audience

This manual provides information to patients in low-acuity hospital-type or home settings, for preparation and maintenance of the system.

Before operating, thoroughly read this manual.

Safety Symbols

Symbol	Definition
	Warning: warnings alert users to potential serious outcomes (injury or adverse events) to the patient, operator or environment
	Caution: cautions inform users to exercise appropriate care for safe and effective use of the product.
	Note: Notes provide additional guidelines or information

ZephyrLIFE Home Indications for Use

ZephyrLIFE Home is **indicated** to receive, transmit, collect, accumulate and display a patient's physiologic signals and other data from a remote location to the healthcare practitioner.

External sensors supply this device with physiologic information such as, but not limited to:

- Blood pressure
- Blood glucose
- Blood oxygen saturation
- Temperature
- Heart Rate
- Respiration Rate
- Position

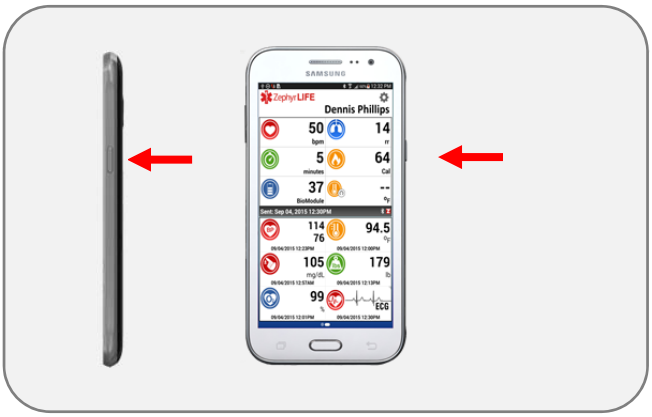
for distribution.

ZephyrLIFE Home Intended Use

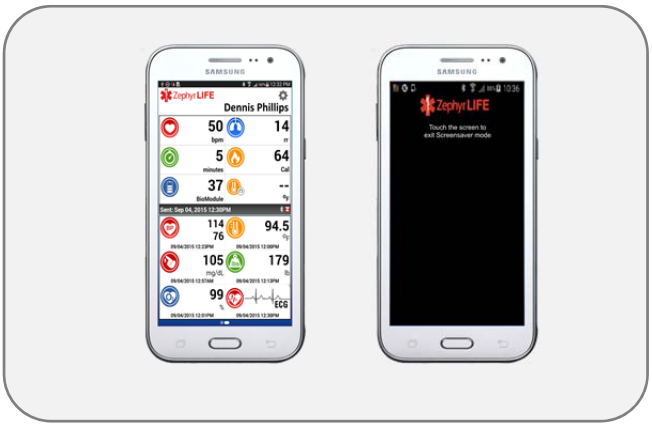
ZephyrLIFE Home Warnings and Cautions

ZephyrLIFE HealthHub™

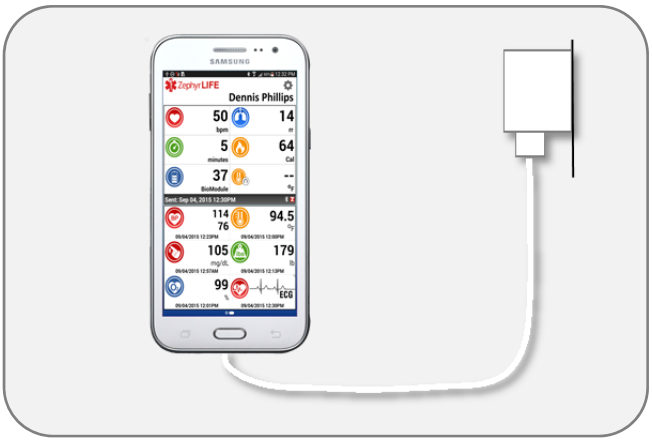
- Press and Hold side button to power ON/OFF.
- Press briefly to turn screen off, and again to turn the screen on.
- ZephyrLIFE will keep running in the background.



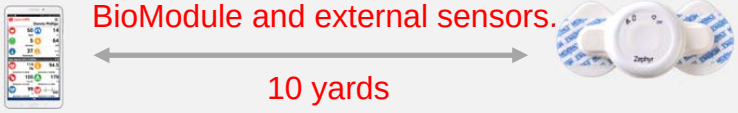
- Tap the icon to start ZephyrLIFE.
- The images shown in this guide are for education purposes only
- Tap the screensaver screen to return to the dashboard



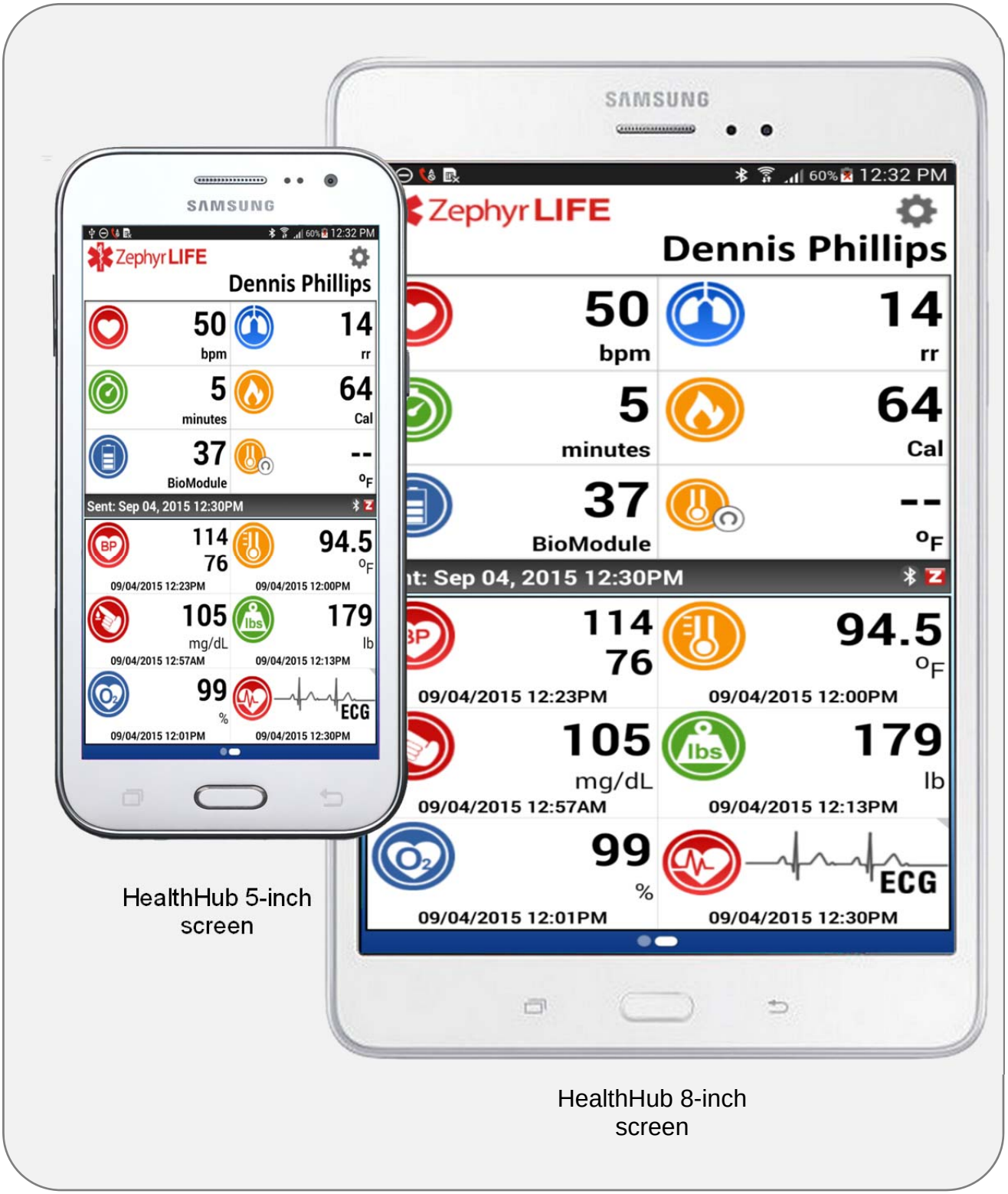
- Keep the HealthHub connected to a charge unit when indoors



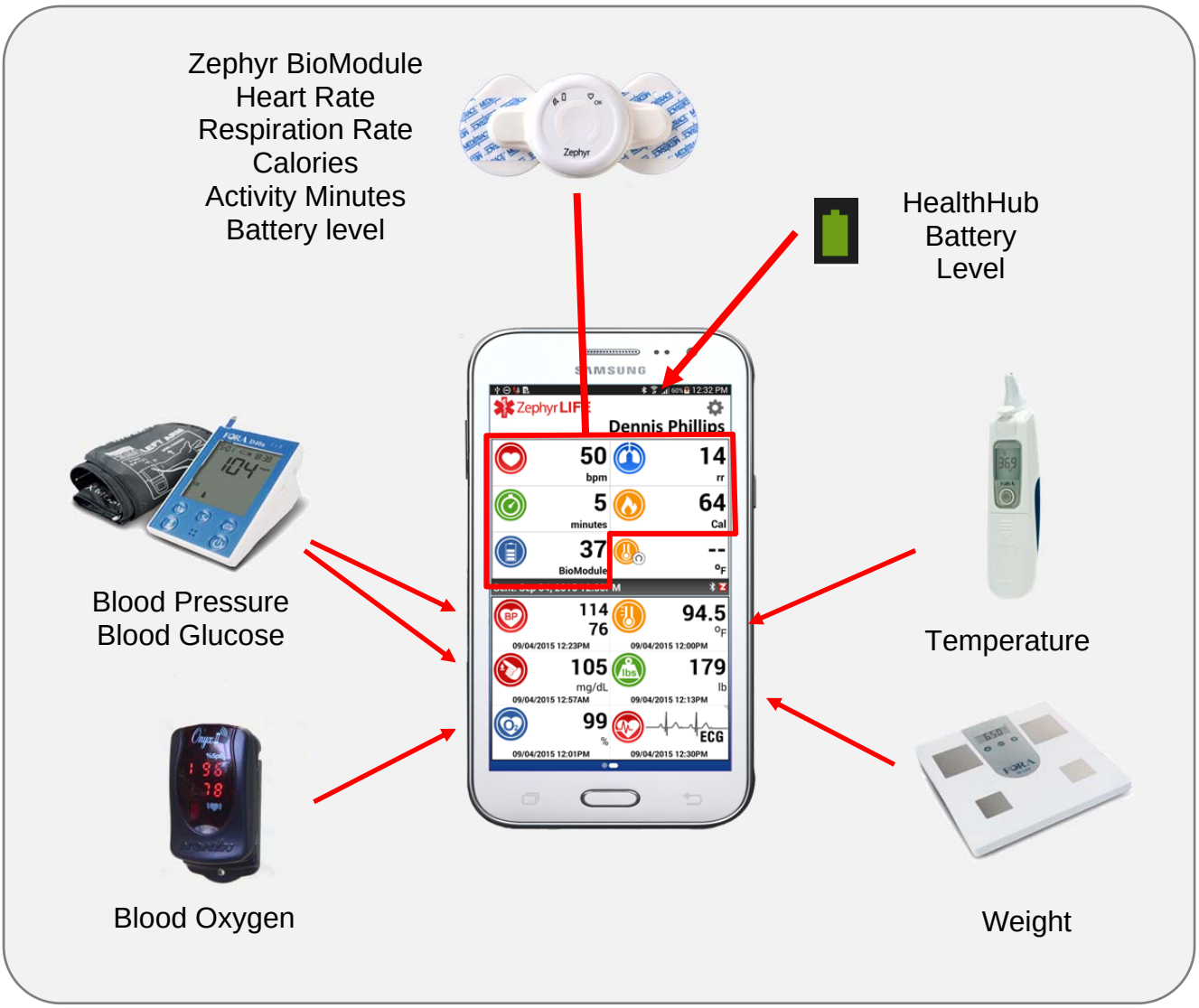
During operation, always keep the HealthHub within 10 yards of the BioModule and external sensors.



ZephyrLIFE HealthHub Device Options



ZephyrLIFE HealthHub Dashboard



	Heart Rate		Respiration Rate
	Activity Minutes		Calories Expended
	BioModule Battery		Not implemented
	Blood Pressure		Temperature
	Blood Glucose		Weight
	Blood Oxygen (SpO_2)		ECG request button

Measure Blood Pressure (Foracare D40d)

- Apply cuff to the arm and start measurement on the device, by pressing the On/OFF button.
- Follow the voice prompt for instructions.

- When complete the new measurement will display with the time it was taken.

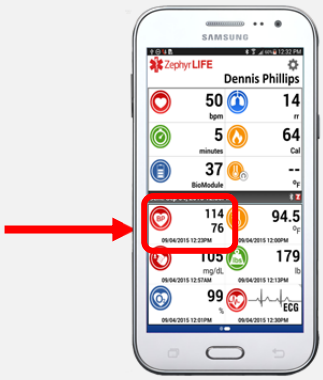
- Detailed instructions for measuring blood pressure and taking test measurements are included in the blood pressure monitor user manual

Check the Blood Pressure monitor user manual for warnings and cautions on its use

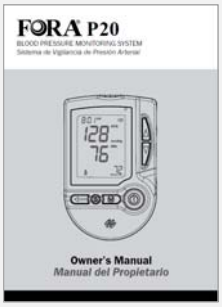
Measure Blood Pressure (Foracare P20)

- Apply cuff to the arm and start measurement on the device, by pressing the On/OFF button.
- Follow the voice prompt for instructions.

- When complete the new measurement will display with the time it was taken.



- Detailed instructions for measuring blood pressure and taking test measurements are included in the blood pressure monitor user manual

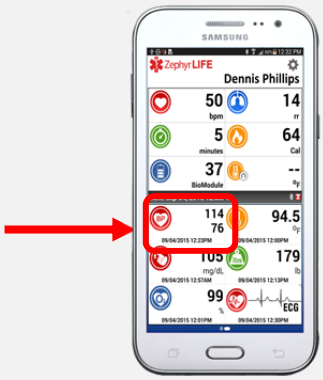


Check the Blood Pressure monitor user manual for warnings and cautions on its use

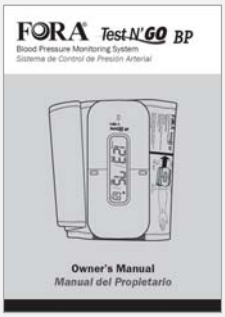
Measure Blood Pressure (Foracare Test N'GO BP)

- Apply cuff to the arm and start measurement on the device, by pressing the On/OFF button on the top edge of the device.

- When complete the new measurement will display with the time it was taken.



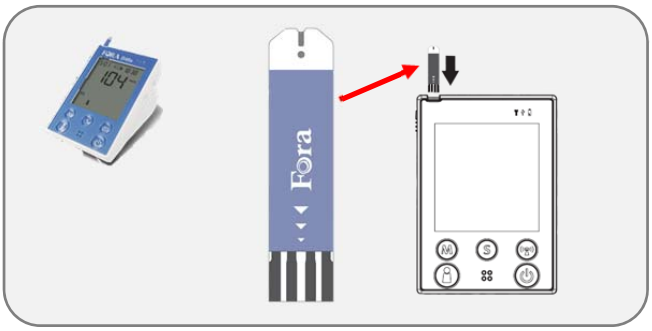
- Detailed instructions for measuring blood pressure and taking test measurements are included in the blood pressure monitor user manual



Check the Blood Pressure monitor user manual for warnings and cautions on its use

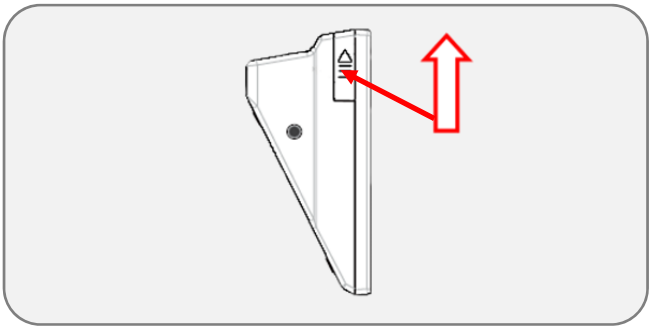
Measure Blood Glucose (Foracare D40d)

- Insert test strip carefully and wait until the glucometer prompts for the blood drop.
- Take a blood sample using the lancing device as instructed.
- Place the blood drop on the strip.
- The glucometer will count down while testing and display the result.



- The result will display on the HealthHub automatically, with the time it was taken.

- Use the side button to eject the Glucose strip.
- As the lancet and test strip may be biohazards, please discard carefully according to your local regulations.

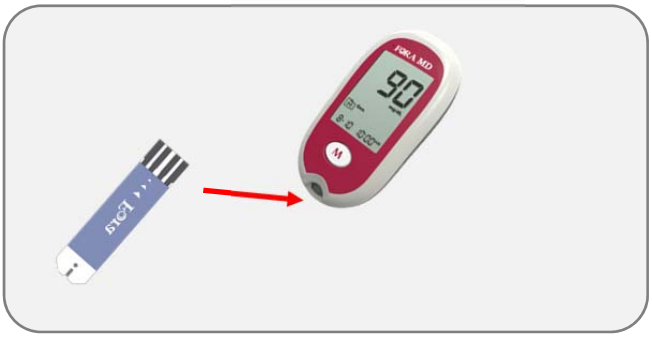


- Detailed instructions for obtaining a blood sample, using the glucometer, troubleshooting and taking test measurements are included in the glucometer user manual.

Check the Blood Glucose monitor user manual for warnings and cautions on its use

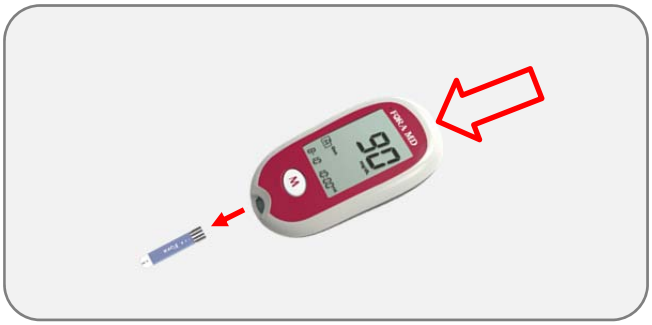
Measure Blood Glucose (Fora MD)

- Insert test strip carefully and wait until the glucometer prompts for the blood drop.
- Take a blood sample using the lancing device as instructed.
- Place the blood drop on the strip.
- The glucometer will count down while testing and display the result.



- The result will display on the HealthHub automatically, with the time it was taken.

- Use the top button to eject the Glucose strip.
- As the lancet and test strip may be biohazards, please discard carefully according to your local regulations.



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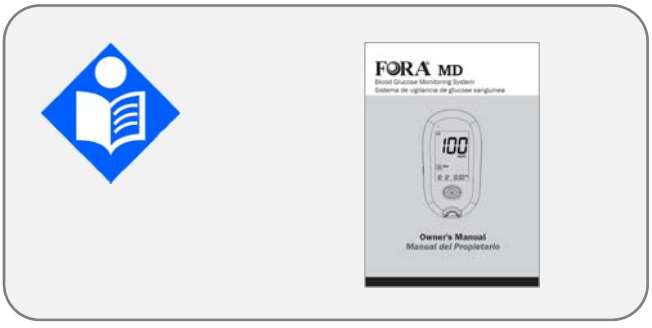
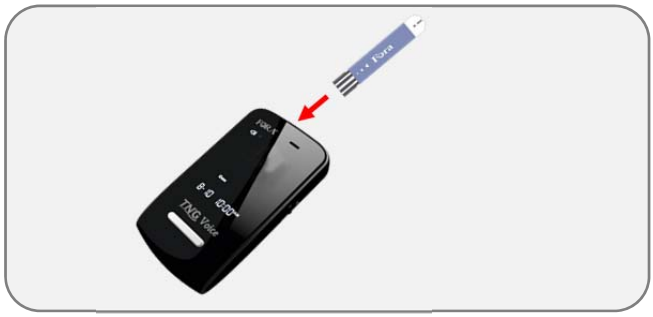


Check the Blood Glucose monitor user manual for warnings and cautions on its use

Measure Blood Glucose (Foracare TN'G Voice)

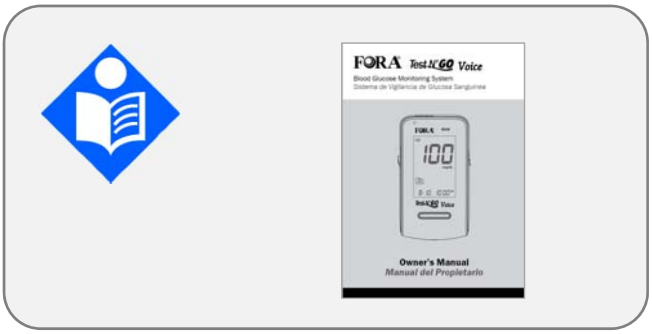
- Insert test strip carefully and wait until the glucometer prompts for the blood drop.
- Take a blood sample using the lancing device as instructed.
- Place the blood drop on the strip.
- The glucometer will count down while testing and display the result.



- The result will display on the HealthHub automatically, with the time it was taken.

- Use the side button to eject the Glucose strip.
- As the lancet and test strip may be biohazards, please discard carefully according to your local regulations.

- Detailed instructions for obtaining a blood sample, using the glucometer, troubleshooting and taking test measurements are included in the glucometer user manual.



Check the Blood Glucose monitor user manual for warnings and cautions on its use

Measure Weight (Foracare W310 Scale)

- Turn on the scale by using the center button or by tapping the weigh platform – wait for the number ‘0.0’ to be displayed.
- Step on the scale and wait for weight to be displayed and stop flashing.

- The weight will display on the HealthHub automatically, with the time it was taken.

- Detailed instructions for setting up the scale and troubleshooting are included in the weigh scale user manual.

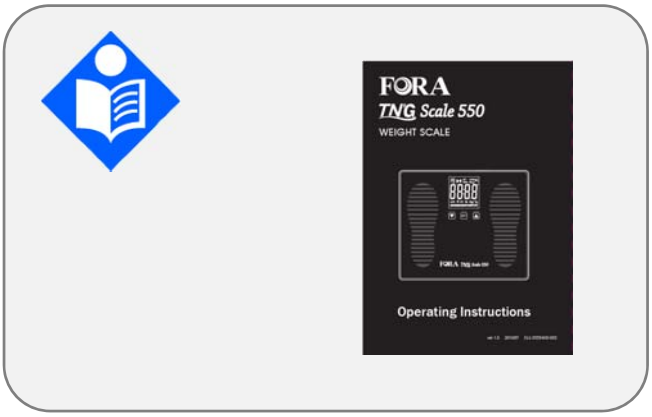
Check the Weigh Scale user manual for warnings and cautions on its use

Measure Weight (Foracare TN'G 550 Scale)

- Turn on the scale by using the center button or by tapping the weigh platform – wait for the number '0.0' to be displayed.
- Step on the scale and wait for weight to be displayed and stop flashing.

- The weight will display on the HealthHub automatically, with the time it was taken.

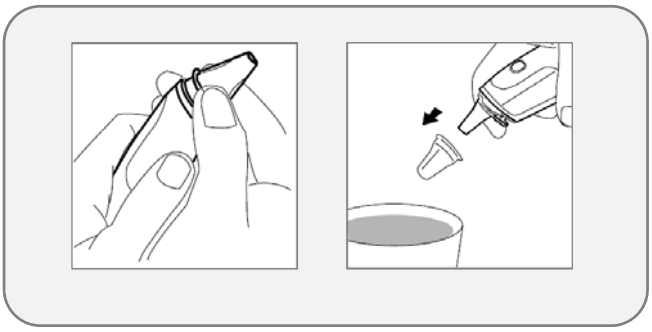
- Detailed instructions for setting up the scale and troubleshooting are included in the weigh scale user manual.



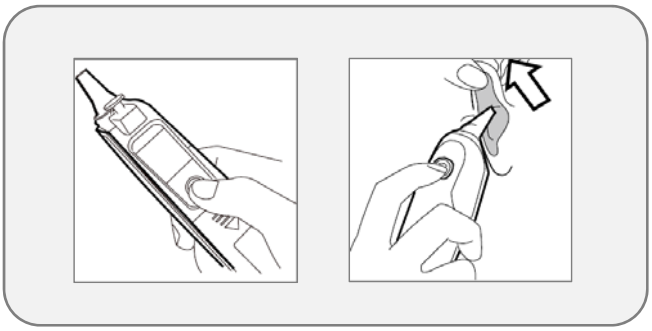
Check the Weigh Scale user manual for warnings and cautions on its use

Measure Temperature

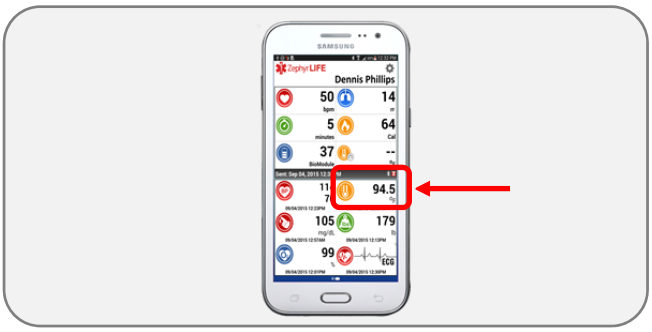
- Fit a new cover on the ear probe. Use only covers supplied by the manufacturer.
- [After taking a reading, dispose of the cover using the eject button].



- Turn on the thermometer using the front button below the display screen. A beep will sound.
- Insert probe gently into ear canal and press the rear button. Hold until another beep indicates temperature taken.



- The result will display on the HeathHub automatically along with the time it was taken

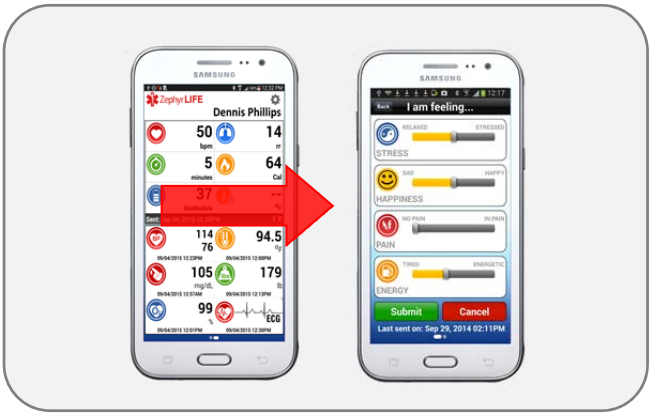


- Detailed instructions for obtaining temperature, using the thermometer, troubleshooting and taking test measurements are included in the thermometer user manual.

Check the Thermometer user manual for warnings and cautions on its use

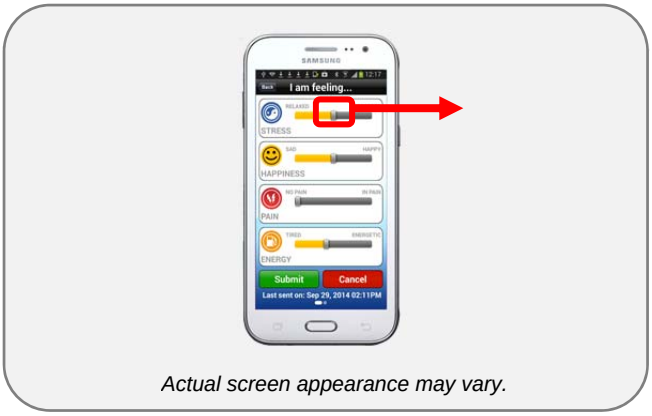
Record Feelings

- Swipe the ZephyrLIFE dashboard from left to right to access the Feelings screen.



- Use the sliders to give an indication of your feelings.
- This is a subjective view for yourself only.
- Use the Submit button 

to send information to the ZephyrLIFE portal.



Actual screen appearance may vary.

- Swipe the Feelings screen in the opposite direction to return to the dashboard, or use the back 

button.

Zephyr BioModule Intended Use

Zephyr BioModule Warnings & Cautions

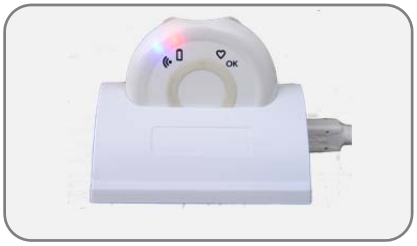
- A quality ECG signal requires that fresh electrode patches and evaluation of skin integrity should occur every 24 hours, or per Care Area guidelines.
- BioModule holder should be disposed of as per care area policy and product instructions.

Zephyr BioModule Contraindications

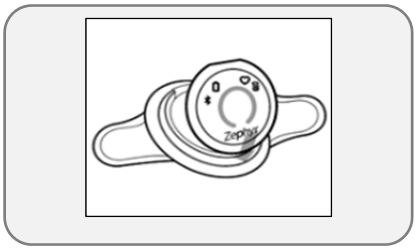
- Not for use with patients fitted with an implanted cardiac device such as an internal pacemaker or automatic defibrillator.

Prepare BioModule for Use

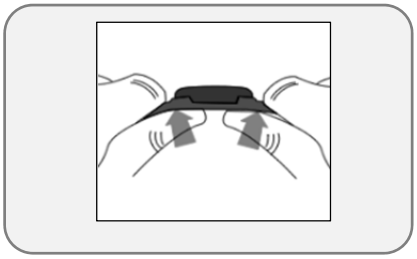
a) Obtain your clean and charged BioModule from the charging cradle
b) Clean BioModule using instructions found in this guide



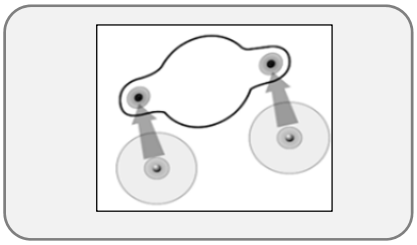
c) Snap the BioModule into the BioModule holder (larger notch in the upper rim). BioModule 'Zephyr' logo at the bottom of the holder.



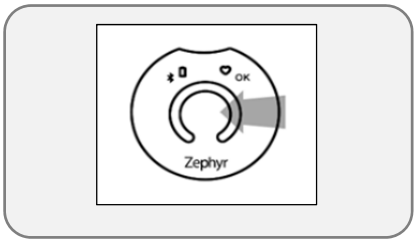
d) To remove, press the BioModule holder from the rear as shown.



e) Verify that the electrode expiration date has not passed and the gel is moist. Keep the electrode package in a zip top bag after opening to keep electrodes moist.
f) Snap two (2) electrodes to the holder. It is ready to apply.



g) Press and hold the device center firmly to turn it on. The red light will light up and the blue light will flash.

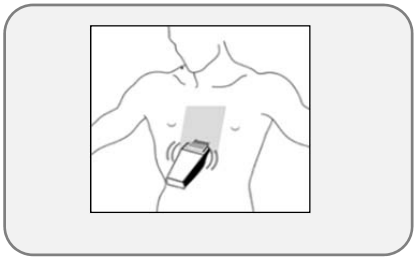


Recommended electrodes:
Covidien Kendall™ 530 Foam

Skin Preparation

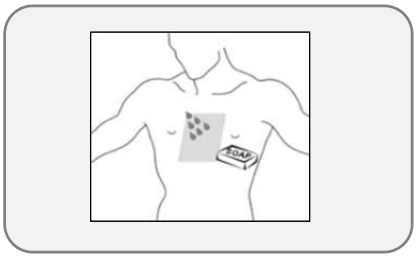
a) Select the area to prepare as indicated in the figure.

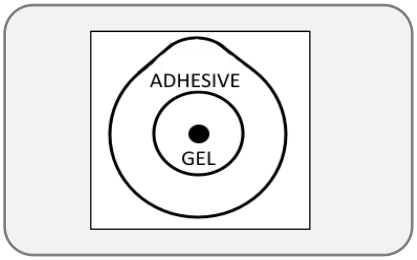
b) Clip hair to make sure electrodes adhere to the skin.



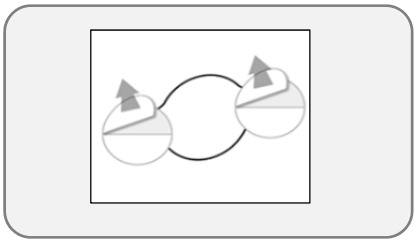
c) Wash skin with soap and water to remove dirt, lotions and dry skin cells. Rinse well.

d) Dry the area with a cloth to remove any hair or soap.



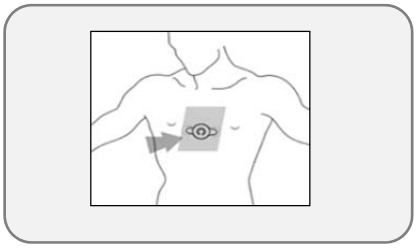


e) Peel the backing from the electrodes.



f) Apply firmly in line with the breast bone as shown, between the sternal notch and the xiphoid process.

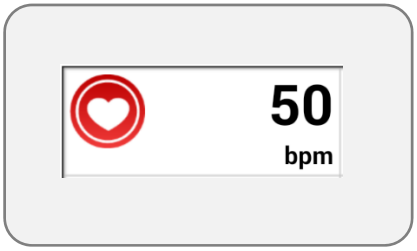
g) The BioPatch may be removed at any time without risk to the wearer. Replace electrodes daily or as instructed.



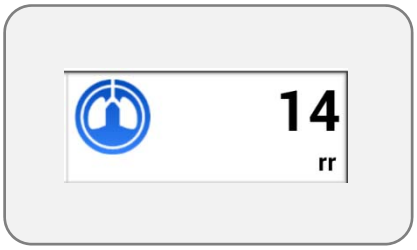
Note: For best signal electrodes should be changed as directed by your prescribing clinician. If the electrode causes skin irritation, please notify your care giver.

BioModule Data

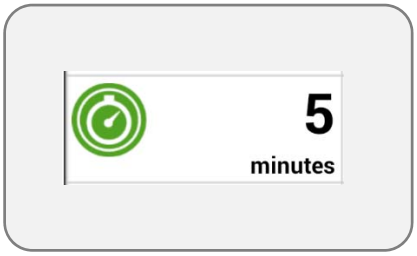
- **Heart Rate** in beats per minute
- Should appear after ~ 1 minute
- Green flashing LED on BioModule
- No heart rate is indicated by '- - ' on the display.



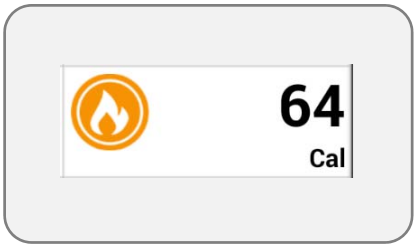
- **Breathing Rate** in breaths per minute
- No breath rate is reported during the first minute
- If after the second minute no breath rate is reported, alternative methods should be considered.
- No breath rate is indicated by '- - ' on the display.



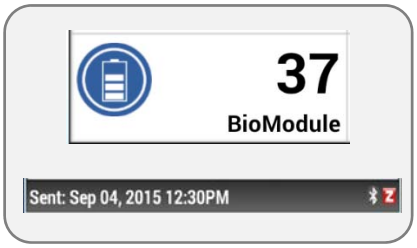
- **Minutes of activity** while wearing BioModule
- Walking effort or equivalent
- Resets at midnight each day



- **Calories burned** while wearing BioModule
- Resets at midnight each day



- **BioModule battery** – percentage full charge remaining
- **Time Stamp** – the date and time the last BioModule information was uploaded to the portal – every 15 minutes



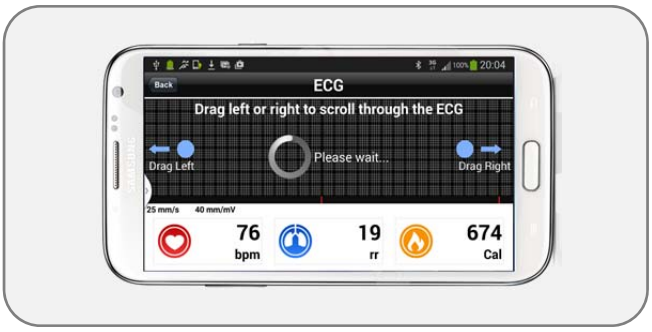
Once the BioModule is attached to the patient and flashing green, the device is functioning properly. This may take up to a minute.

Measure ECG

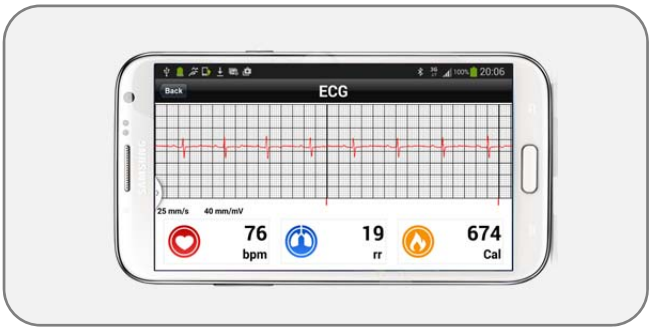
- Sit down and remain still while taking ECG.

- Touch the ECG button to request a new ECG strip.

- The ECG screen will display.
- Be careful not to touch the screen again as it will stop the ECG from being acquired.
- If the BioModule has recently been applied, a message may display asking you to wait 1 minute.



- ECG will be displayed, with time measurement taken, and uploaded to the web portal.
- Touch the screen again to return to the main screen (or the back button).



If you experience chest pain, or signs and symptoms of an acute problem, call 911 or follow the instructions of your physician

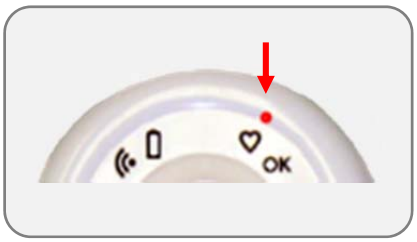
BioModule Light Indicators

a) **GREEN**: flashing – working normally. Data is transmitting.

b) **BLUE**: flashing – loss of Bluetooth signal. Move closer to the HealthHub. Confirm HealthHub application is running.

c) **ORANGE**: Flashing – low battery. Recharge in cradle.

d) **RED**: constant – No heart rate detected. Check electrode connection. Re-prep skin and apply fresh electrodes if necessary.



In Charging Cradle:

a) Flashing Orange = Charging (1 hr to 90%)
b) Constant Orange = Charged (3 hrs to 100%) Ready to use.

Once the BioModule is attached to the patient and flashing green, the device is functioning properly. This may take up to a minute.

Onyx® II Model 9560 Finger Pulse Oximeter Indications for Use

The Nonin Onyx II Finger Pulse Oximeter is a small, lightweight, wireless device indicated for use in measuring and displaying functional oxygen saturation of arterial haemoglobin (%SpO_2) and pulse rate of patients who are well or poorly perfused.

It is intended for spot-checking of adult and pediatric patients on fingers (other than the thumb) between 0.3 – 1.0 inch (0.8 – 2.5 cm) thick.

The device's intended use environments include hospitals, clinics, long-term care facilities, skilled nursing facilities, emergency medical services and home healthcare services

Federal Law restricts this device to sale by or on the order of a licensed practitioner.

Onyx® II Model 9560 Finger Pulse Oximeter Contraindications

- Do not use the device in an MR environment, in an explosive atmosphere, or on infant or neonatal patients.
- This device is not defibrillation proof per IEC 60601-1

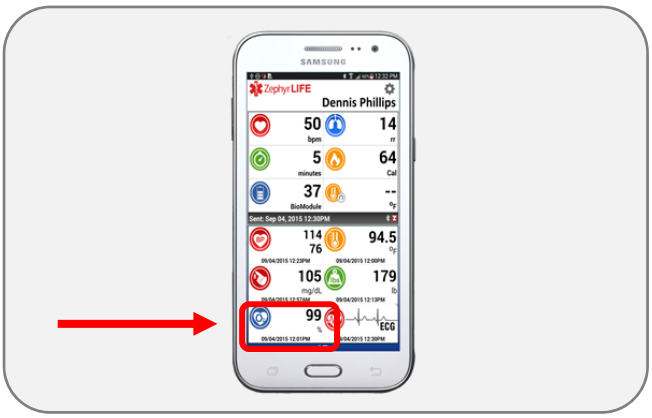
Onyx® II Model 9560 Finger Pulse Oximeter Warnings

Further information can be found in the Onyx II® User Manual

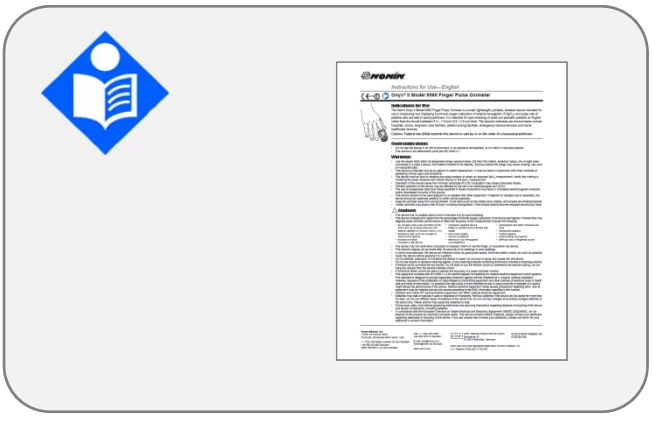
Measure Blood Oxygen

- Insert index finger in sensor.
- Wait until the red lines on the top row stop flashing.
- Do not wear dark nail varnish when using the oximeter as this will affect its ability to take a reading.

- The reading will display on the HealthHub automatically, with the time it was taken.



- Detailed instructions for taking blood oxygen measurements and troubleshooting are included in the pulse oximeter user manual.

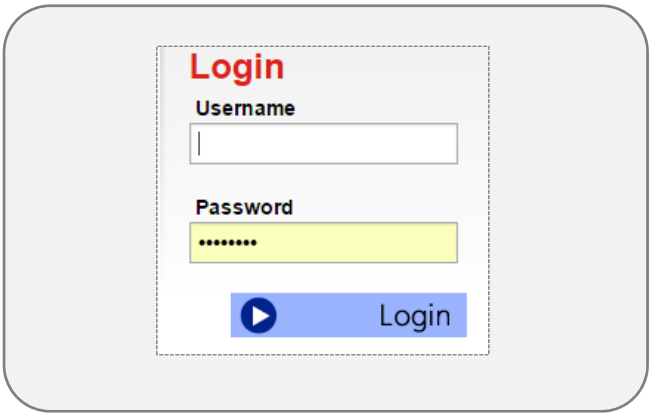


Please check the Pulse Oximeter user manual for warnings and cautions on its use

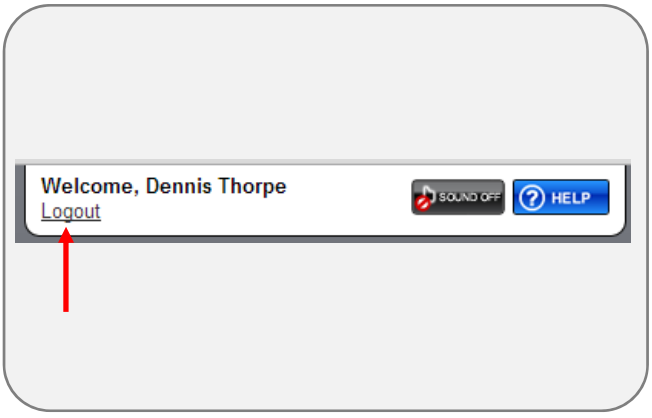
Accessing the Portal

- Go to the web address supplied by your administrator

- Use the login form on the right
- You will need to use the ***Username*** and ***Password*** provided to you



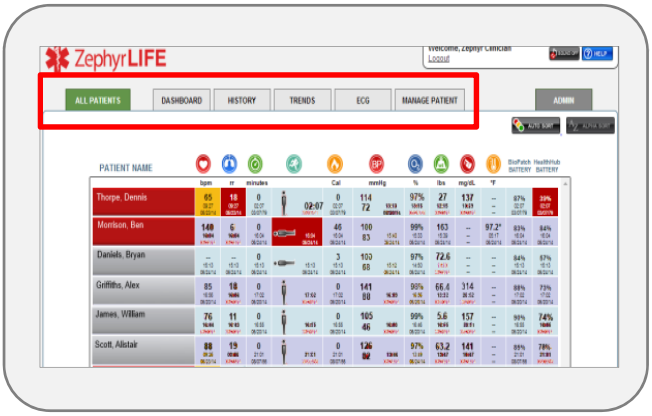
- When you have finished accessing the portal, log out by clicking Logout at the top of the screen



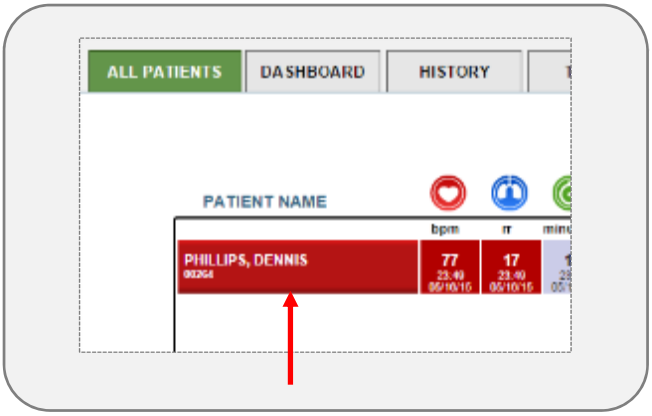
Supported web browser is Chrome

Navigating the Portal Screens

- Use the tabs at the top of each screen.

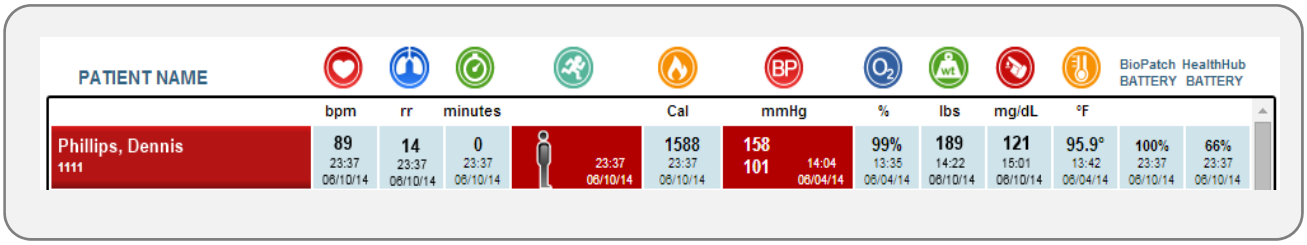


- In the All Patients tab select the patient name to open the specific patient Dashboard tab.



- **Auto Sort** – (default) – highest (red, yellow) alert patients at the top.
- **Alpha Sort** – alphabetical order by last name.
- **Help** – provides access to the Quick Reference

All Patients Tab Parameters

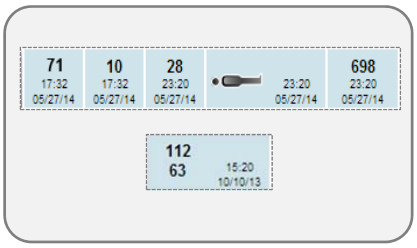


Update Time	Data	Description/Units
Once per minute for initial 15 min after power-on, then every 15 min OR Last alert generated [Last Update value]	Heart Rate	Beats/minute
	Respiration Rate	Breaths/minute
	Activity Minutes	Minutes of activity since midnight – resets at zero every midnight
	Posture	Icon: Walk, upright, lying down
	Calories	Calories expended during the selected time period
	Blood Pressure	Systolic/Diastolic in mmHg
Last measurement [Values are individually timestamped]	SpO_2	Peripheral blood oxygen saturation (%)
	Weight	lbs
	Blood Glucose	mg/dL
	Temperature	Degrees Fahrenheit

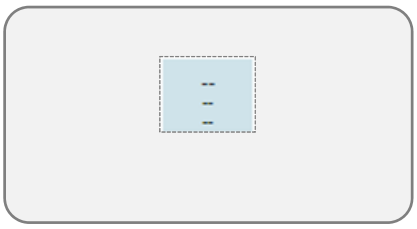
Data Updates – Reading the All Patients Tab

- Active Alerted subject/invitees are show at the top of the list.

- BioModule Data updated every 15 minutes.
- External sensor readings show time and date of last measurement.



- '- -' displays if no valid measurement taken using an external sensor.



- Blue cell – a measurement has been missed inside a period set in the portal.

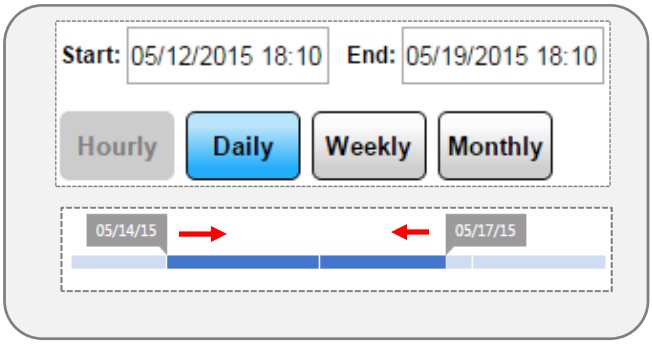
- Blue row – no data for 1/3/7 days, set in the portal.

- You will only see this screen unless invited to the Care Circle of another patient.

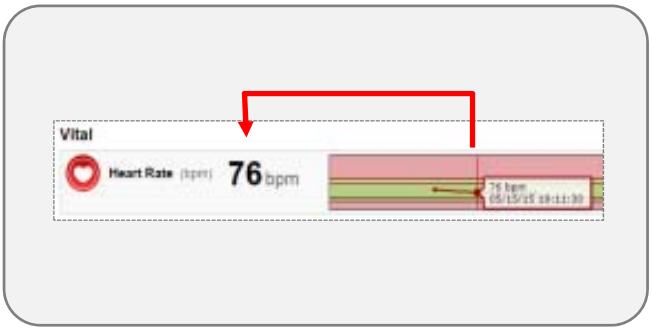
Dashboard

- Display latest data OR cursor location on trend graph.
- Select the patient's name from the list on the left (single entry in example).

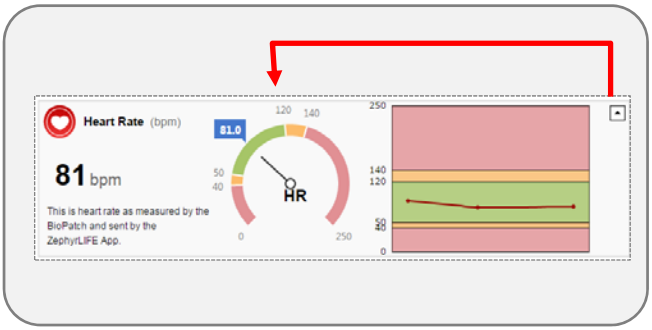
- Select Start and End dates and time span button.
- Defaults: Previous 7 days/daily.
- Drag flags above graph to zoom in.



- Mouse over graph data point to show recorded values.
- No mouse = last received value.



- Expand any graph using the ▾ arrow to show sweep scale.
- Green/yellow/red coloring reflects alert thresholds set for each vital sign.



History

- Each row shows the same data shown on the All Patients tab.

- Select time interval to display.

- Show or hide alerts.
- Alerting cells are red or yellow.

- Alert Column Indicator – use to clear a single alert for that column.

Alert

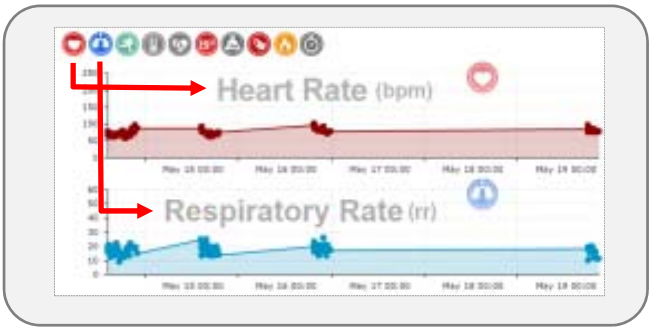
Cleared Alert

Trends

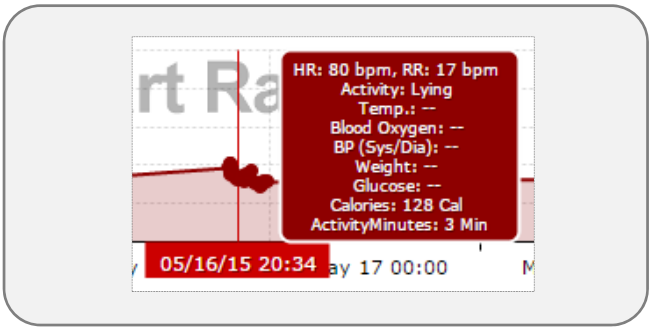
- Patient history as a line graph.

- Select time interval to display.

- Select icons to show or hide graphs
- Grey icon = graph not displayed

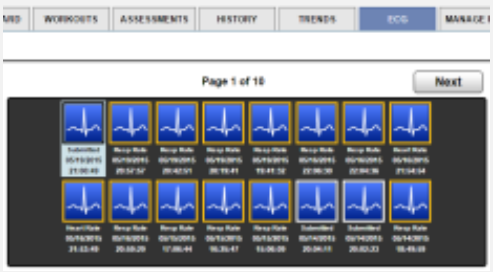


- Mouse over any data point on graph to show recorded values in a callout.

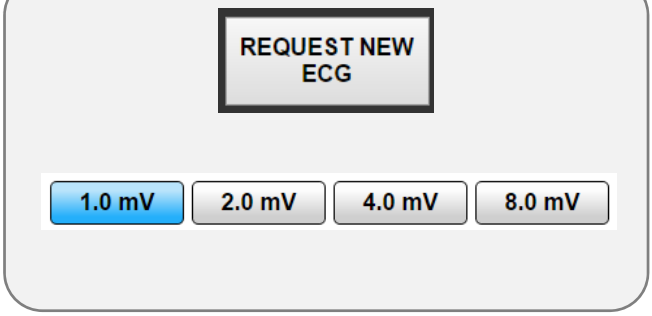


ECG

- ECG strips are generated by button request on screen (authorization required), or automatically when a Heart Rate or Breathing Rate alert is triggered or when submitted by patient on the HealthHub.
- Thumbnail frame colors
  - White = manual request or submit
  - Yellow/Red = auto by alert trigger

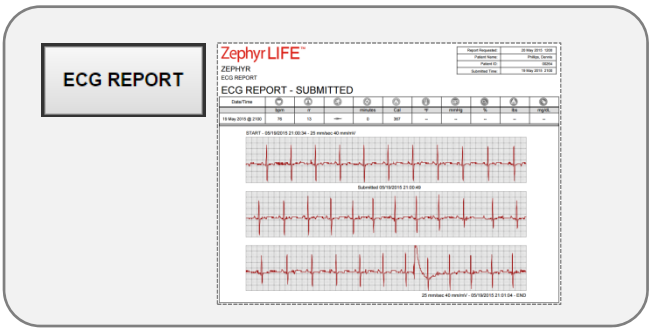


- Select from thumbnail archive or
- REQUEST NEW ECG by clicking on button
- Set vertical scale (mV) of the strip paper



- Data are 3 x 10 second strips – 15 seconds before & after request or trigger.

- Use the ECG Report button to generate a report

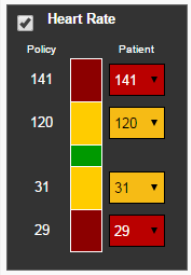


Manage Patient

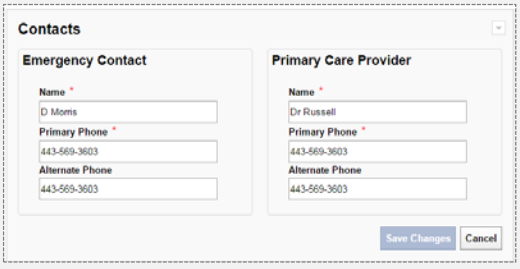
Patient Demographics

- Update personal details
- Email will be the patient's own login

- You may have been given permission to change your alert thresholds, or they may be inactive.
- Alerts display as colored cells in the Portal.
- Alerts are for information only; they are not warnings.
- You should consult your clinician before changing any alert levels.

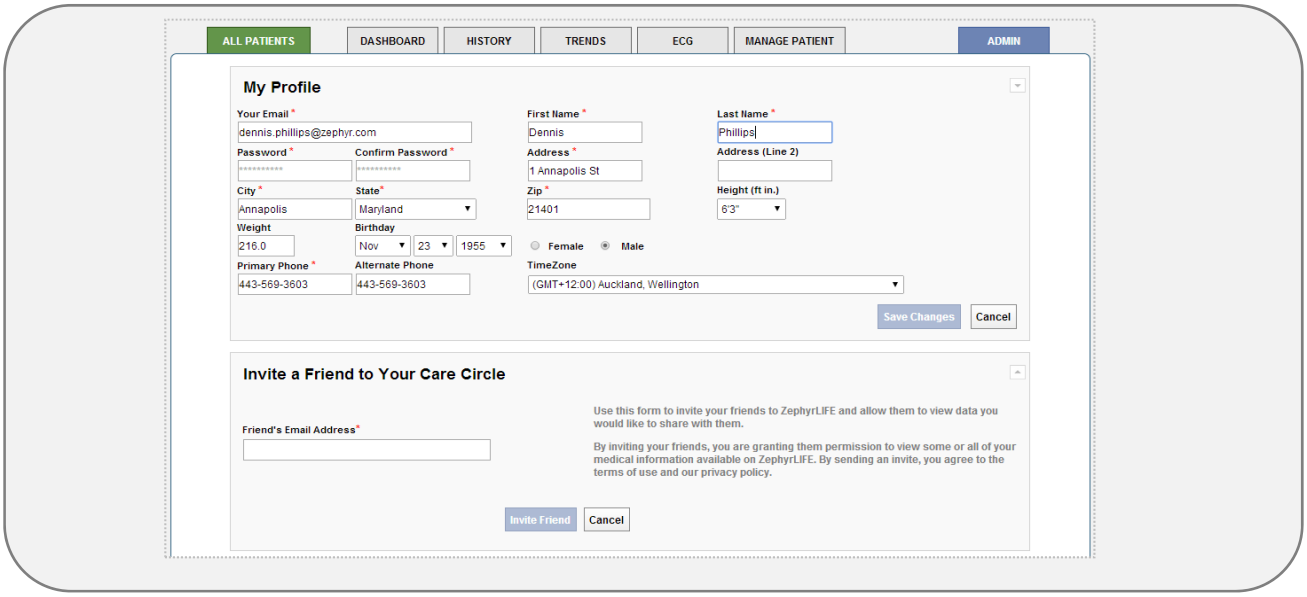


- Emergency Contact details are at the foot of the page



- Alerts are generated to inform a credentialed caregiver and are not intended by the manufacturer to suggest any action to the caregiver or user.
- An alert is for information only – it is not an alarm.

Care Circle

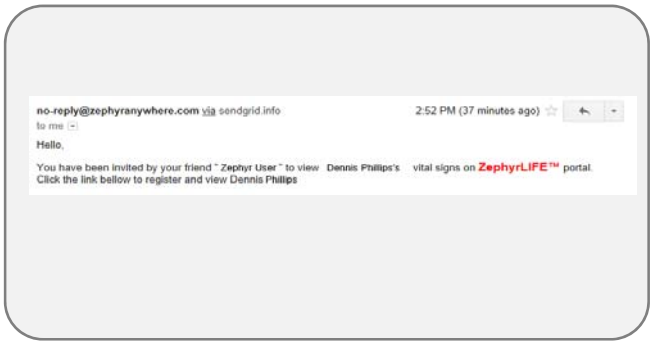


- Update all Patient details in the My Profile section.

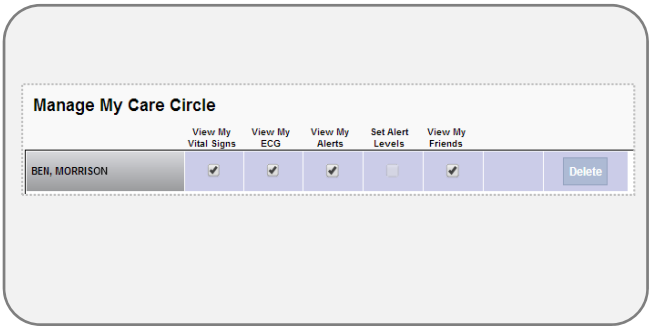
INVITE A FRIEND

- A patient logged in to the portal can use the Admin tab to send an email invite to a friend to register to view their data. Clinicians do not see this view.

- An email invitation will be sent to the friend, with a link to a registration page.

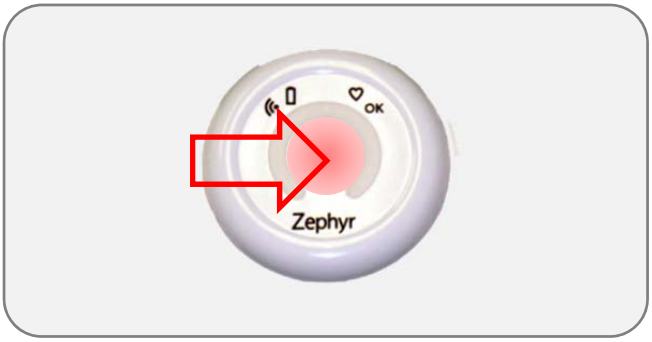


- The patient can use their Admin tab to set what their friend can see when logged in to the portal.

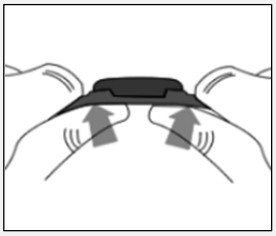


To Replace a Discharged BioModule

- Remove the BioModule from the subject.
- Turn off the BioModule by pressing the center for five seconds or until all the lights turn off.



- Remove the BioModule from the holder by pressing firmly on the back while retracting on the snap wings as shown.



- Insert the BioModule in the charging cradle, making sure the crescent notch is upward as shown.
- The cradle is powered by a wall plug adaptor.

- A full charge of a fully-depleted battery will take approximately 3 hours.
- A solid non-flashing orange light means fully charged.

Care & Cleaning of the BioModule and BioModule Holder

- The BioModule holder is for single patient use and can be reused by that patient.
- ECG electrodes may be disposed in general home waste.

- The BioModule and BioModule Holder are reusable and should be surface cleaned with one of the products below.
- Wipe BioModule and BioModule Holder with a cloth soaked in bleach *or* peroxide solution. Let air dry.

Recommended cleaning product options

- Sani-Cloth HB
- Sodium Hypochlorite (8.25% bleach, diluted 1:10 to 1:100)
- Hydrogen Peroxide (3% solution)

Sani-Cloth is a registered trade mark of Professional Disposables International, Inc.

Sani-Cloth HB®

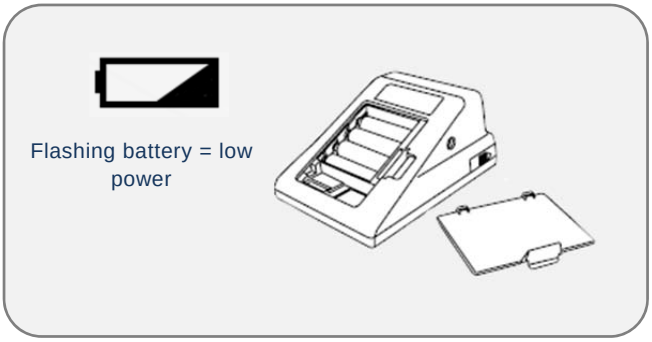
Hydrogen Peroxide

Bleach

Consult the instructions supplied with each cleaning product for appropriate cleaning procedure

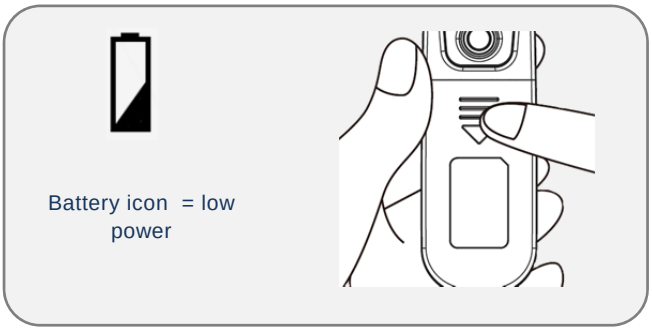
Changing batteries on devices

- Fora D40 Blood Pressure/Glucometer.
- 4 x AA batteries.
- Flashing battery symbol means batteries are low.



- After battery replacement, take a measurement.
- The first measurement after changing batteries will be discarded and a message displayed on the HealthHub.
- Repeat to take a valid measurement.

- Fora IR20 Thermometer.
- 2 x AA batteries.
- Constant battery symbol means batteries are low.

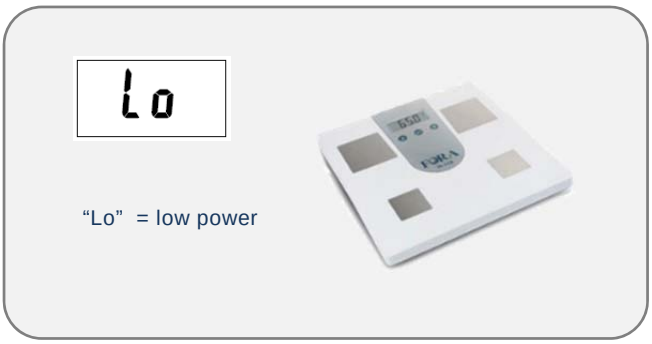


- After battery replacement, take a measurement.
- The first measurement after changing batteries will be discarded and a message displayed on the HealthHub.
- Repeat to take a valid measurement.

For detailed instructions on changing the batteries in optional sensors, please read the manufacturer's manual

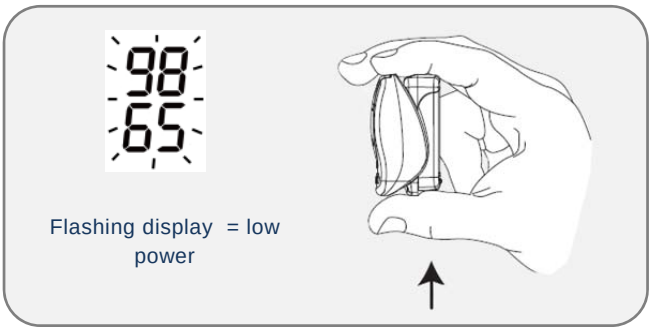
Changing batteries on devices

- Fora W310 Weight Scale.
- 4 x AA batteries.
- “Lo” display means batteries are low.



- After battery replacement, take a measurement.
- The first measurement after changing batteries will be discarded.
- Repeat to take a valid measurement.

- Nonin 9560 Pulse Oximeter
- 2 x AAA batteries.
- Flashing display means batteries are low.
- Squeeze as shown to release battery compartment.



- After battery replacement, take a measurement.
- The first measurement after changing batteries will be discarded.
- Repeat to take a valid measurement.

For detailed instructions on changing the batteries in optional sensors, please read the manufacturer’s manual

Changing batteries on devices

- ForaTN'G 550 Weight Scale.
- 4 x AA batteries.
- "Lo" display means batteries are low.

"Lo" = low power

- After battery replacement, take a measurement.
- The first measurement after changing batteries will be discarded.
- Repeat to take a valid measurement.

- Fora MD Glucometer
- 2 x AAA batteries.

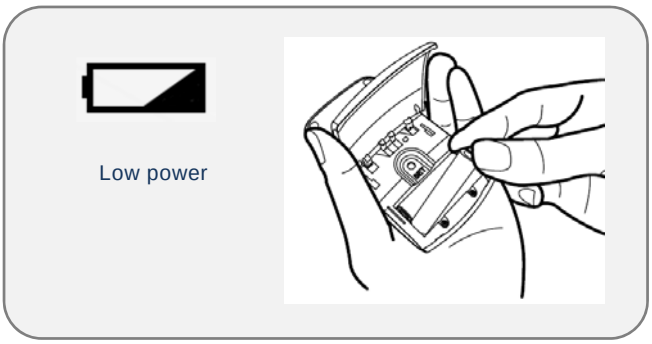
Low power

- After battery replacement, take a measurement.
- The first measurement after changing batteries will be discarded.
- Repeat to take a valid measurement.

For detailed instructions on changing the batteries in optional sensors, please read the manufacturer's manual

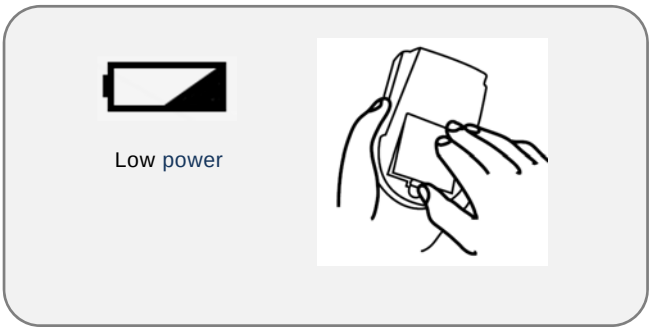
Changing batteries on devices

- Fora Test N'GO Voice.
- 2 x AAA batteries.



- After battery replacement, take a measurement.
- The first measurement after changing batteries will be discarded.
- Repeat to take a valid measurement.

- For a P20 Blood Pressure Monitor
- 4 x AAA batteries.



- After battery replacement, take a measurement.
- The first measurement after changing batteries will be discarded.
- Repeat to take a valid measurement.

For detailed instructions on changing the batteries in optional sensors, please read the manufacturer's manual

Changing batteries on devices

- Fora Test N'GO BP.
- 4 x AAA batteries.

- After battery replacement, take a measurement.
- The first measurement after changing batteries will be discarded.
- Repeat to take a valid measurement.

For detailed instructions on changing the batteries in optional sensors, please read the manufacturer's manual

Troubleshooting Tips

Question	What to do
How do I know if the BioModule is fully charged?	The orange light is steady, not flashing when in the charging hub or cradle. See BioModule Light Indicators page.
How long does it take to charge?	1 hour for 90% charge and 3 hours for 100%. See BioModule Light Indicators page.
What does it mean if the red light on the BioModule is constantly on?	A steady red light indicates no heart rate was detected – check that the BioModule holder is firmly attached to the electrodes and that the electrodes are securely attached your chest. See Page 32
What does a flashing blue light mean?	A flashing blue light indicates a loss of radio transmission from the BioModule to the HealthHub. Move closer to the HealthHub, or locate it in a more central room of your home. See BioModule Light Indicators page.
Is it important to place the BioModule in the pictured positions?	Yes, to get the most accurate data it is very important to position as shown. See Skin Preparation page.
What do I do with my HealthHub while wearing the BioModule?	Keep it in the base plugged into an outlet in the same room, or carry the HealthHub with you if you go outside. Make sure the HealthHub is charged before leaving. The HealthHub can lose communication with the BioModule if separated by more than 10 yards.
A message appears on the HealthHub “No Internet Connection Available”.	Make sure that the HealthHub has wireless data connectivity. Re-start the HealthHub and the ZephyrLIFE application.
A message appears on the HealthHub “ZephyrLIFE Patient isn’t responding, do you want to close it?”	Re-start the HealthHub and the ZephyrLIFE application.
Different values are shown on the HealthHub from the peripheral device	Repeat measurement.
HealthHub and portal do not display data from the Fora device after multiple measurements	Remove and reinsert the batteries from Fora device and take measurement. The first measurement will be discarded, take a second measurement.

Specifications

BioModule Prescription Device	
Heart Rate	30 – 240 bpm ±1bpm static (R-R interval)
Breathing Rate	5 – 50 brpm ±1brpm static
Battery Performance	
Type	Rechargeable Lithium Polymer, 3.6 – 4.2V
Operating	24 hours minimum when new and fully charged *Place in charger 24 hours if unused for 3 months. Charge periodically if unused to avoid full discharge state*
Battery Charging	
Charge Time	1 hr to 90% capacity, 3 hrs to 100% capacity
Single Device Charge cradle	USB connector provided AC Adaptor, 100-240V input 5V/0.5A output
5 Device Charge cradle	100-240V input, 7.5V /3.0A output power supply provided
Classifications per IEC 60601-1	
Installation & Use	Portable, body-worn
Degree of Protection	Type CF-Applied Part
Supply Connection	Internally powered
ECG type (BH3-M1)	Ambulatory Electro Cardio Graph (AECG Type 3) as per ANSI/AAMI EC38:1998 compliance
ECG type (BH3-M2)	Ambulatory Electro Cardio Graph (AECG) as per IEC 60601-2-47: 2012 compliance
Transmitter	
Bluetooth Compliance	Version 2.1 + EDR
Operating Frequency	2.4 - 2.4835 GHz
Output Power	10 dBm
Antenna type	Internal
Operating Range	10 yards
Modulation Type	FSK
FCC ID	VZ6-BH3
Electromagnetic Compliance	
Emissions	IEC 60601-1-2:2007
Immunity	IEC 60601-1-2:2007
Environmental (Operating)	
Temperature	-20º C to +45º C (-4º F to 113º F) inclusive
Temperature - charging	0º C to +45º C (32º F to 113º F) inclusive
Relative Humidity	15% to 95% non-condensing
Ingress Protection	IP67 – protected from dust and against the effect of immersion in water to depth between 15 cm and 1 meter (6 in to 3 ft)

Environmental (Storage & Transportation)	
Temperature	-20º C to +45º C (-4º F to 113º F) inclusive
Relative Humidity	15% to 95% non-condensing
Atmospheric Pressure	12kPa to 107kPa
Service Life	
BioModule Battery	300 charge cycles minimum
Maintenance	Other than cleaning and charging, no other maintenance is required.
BioModule Holder	Single Patient use
ECG electrodes	Single use

Disposal	
Return	The BioModule, charge cradle and BioModule holder contain no hazardous components. All electrical components are lead-free. Zephyr Technology will undertake to dispose of any end-of-life components which are returned to their facility.
Local Disposal	Where specific provision is made in a particular region for disposal and recycling of electrical goods, Zephyr advises following local guidelines for conscientious disposal of equipment.
WEEE	Zephyr BioModule is WEEE compliant
Dimensions	
BioModule	48 x 46 x 10 mm (1.9 x 1.8 x 0.4 in)
Holder	90 x 50 x 10 mm (3.5 x 2.0 x 0.4 in)
Weight	
BioModule	18 grams (0.63 oz)
Holder	14 grams (0.49 oz)

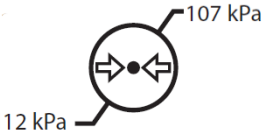
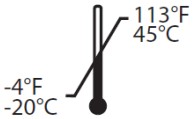
Symbols on Device

	Blue LED – Bluetooth transmit status/error
	Orange LED – low battery indication/charging indication
	Red LED – Heart Rate detection status/error
OK	Green LED – normal operations indication

Symbols on Device Label

BioModule	Manufacturer's designation for device
REF	Device Model
SN	Device Serial Number XXXXXX
	Consult user manual before use
	Type CF-Applied Part
IP67	Ingress Protection Rating
AECG Type 3	Device Type [Ambulatory ECG Type 3]
	WEEE Europe
	Contains radio transmitter (non-ionizing radiation)
	FCC radio emissions compliance
FCC ID	Zephyr BioModule ID

Symbols on Shipping Label

	Prescription-only device
	Read instruction manual (this manual) before use
	Transport atmospheric pressure range 12kPa – 107 kPa
	Transport humidity range 15 – 95% RH
	Transport temperature range -4º - 113ºF / -20º - 45ºC
	Keep dry

Accessories

The Zephyr BioModule should only be used in conjunction with the following accessories, supplied with the system kit:

Component	Part Number	Description
Zephyr BioModule BH3-M1	9607.0216	Zephyr BioModule
Zephyr BioModule BH3-M2	9607.0296	Zephyr BioModule
BioModule Holder	9607.0207	White holder, stainless steel snaps
Single charge cradle	9800.0221	White single BioModule charge cradle
USB cable	0015.0051	USB cable for single BioModule charge cradle
USB A/C Adaptor	0010.0119	AC adaptor for single BioModule cradle
5 Device charge cradle	9607.0215	White charge cradle for 5 BioModules with power supply
Nonin 9560BT Onyx II	9607.0231	Pulse Oximeter SpO_2 sensor
Foracare W310b	9607.0223	Weigh Scale
Foracare TN'G 550	9607.0282	Weigh Scale
Foracare IR20b	9607.0230	Infrared Ear Thermometer
Foracare IR20b V4	9607.0285	Infrared Ear Thermometer
Foracare D40d	9607.0222	Blood Pressure / Blood Glucometer sensor
Foracare D40d V4	9607.294	Blood Pressure / Blood Glucometer sensor
Lancet Pen	9607.0233	Foracare Lancet Pen for D40d
Foracare P20	9607.0286	Foracare Test N'Go Blood Pressure Cuff
Fora MD	9607.0289	Blood Glucose Sensor
For a TN'G Voice	9607.0283	Blood Glucose Sensor
ZephyrLIFE HealthHub 5"	9607.0278	ZephyrLIFE HealthHub and installed software
ZephyrLIFE HealthHub 7"	9607.0277	ZephyrLIFE HealthHub and installed software

Component	Part Number	Description
BP Cuff Large	9607.0107	Large BP cuff for D40d
BP Cuff Wide Range	9607.0108	Wide Range BP cuff for D40d
BP Cuff Small	9607.0109	Small BP cuff for D40d
ECG Electrode	9607.0104	Covidien™ Kendall™ 530 Foam Electrode, pack of 30
IR20b Lens Filter	9607.0235	Pack of single-use lens filters for ear thermometer
IR20b V4 Lens Filter	9607.0292	Pack of single-use lens filters for ear thermometer
BG Test Strips	9607.0232	Pack Test Strips for D40d blood glucose
BG Test Strips	9607.0291	Pack 50 Test Strips for Fora MD blood glucose
BG Test Strips	9607.0284	Pack 50 Test Strips for Fora TN'G Voice blood glucose
Lancets	9607.0234	Pack Foracare lancets for lancet pen
Control Solution	9607.0237	Blood control solution for D40d glucometer calibration
Control Solution	9607.0287	Blood control solution GDH
Control Solution	9607.0288	Blood control solution GOD

Manufacturer's Declaration and Guidance

Electromagnetic Emissions

Electromagnetic Emissions Guidelines and Compliance

Guidance and Manufacturer's Declaration—Electromagnetic Emissions **(IEC 60601-1-2:2007, Table 1)**		
The BioModule is intended for use in the electromagnetic environment specified below. The customer or the user of the BioModule should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment Guidance**
RF emission CISPR 11	Group 1, Class B	BioModule uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic Emission IEC 61000-3-2	N/A	N/A
Voltage fluctuation/ flicker emissions IEC 61000-3-3	N/A	N/A

Electromagnetic Immunity

Electromagnetic Immunity Guidelines and Compliance

Guidance and Manufacturer's Declaration—Electromagnetic Immunity (IEC 60601-1-2:2007, Table 2)			
The BioModule is intended for use in the electromagnetic environment specified below. The customer or the user of BioModule should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Recommended Separation Distance Calculations

Guidance and Manufacturer's Declaration—Electromagnetic Immunity (IEC 60601-1-2:2007, Table 4)			
The BioModule is intended for use in the electromagnetic environment specified below. The customer or the user of BioModule should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 KHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Not applicable 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the BioModule, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey[a] should be less than compliance level in each frequency range[b] Interference may occur in the vicinity or equipment marked with the following symbol: 

Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If measured field strength in the location in which the BioModule is used exceeds the applicable RF compliance level above, the BioModule should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BioModule.

[b] Over the frequency range 150 kHz to 80 MHz, fields strengths should be less than 3 V/m

Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and BioModule

The BioModule is intended for use an electromagnetic environment specified below in which radiated RF disturbances are controlled. The customer or user of the BioModule can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BioModule as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W (watts)	Separation distance according to frequency of transmitter m (meters)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

FCC Declaration

NOTE: The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment.

This device complies with Part 15 of FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation.

Any computer used in conjunction with this device must be covered by a Declaration of Conformity or must be FCC certified in its own right.

Warranty

The product is tested and validated with the components which are supplied with the ZephyrLIFE Home Kit. Substituting any portion of the kit may alter functionality of the kit. Use only parts which are supplied with the kit.

Changes or modifications to the BioModule and/or BioModule Holder may void the user's authority to operate this equipment.

Appendix I Active Patient Monitoring

A device is considered used for active patient monitoring when it is:

- relied upon for information necessary to make an immediate medical decision, or
- used for continuous patient monitoring.